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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/730,034	12/09/2003	Takanori Okura	OKURA=1B	3030

7590 04/08/2005

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EXAMINER

LIETO, LOUIS D

ART UNIT PAPER NUMBER

1632

DATE MAILED: 04/08/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/730,034

Applicant(s)

OKURA ET AL.

Examiner

Louis D. Lieto

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-7 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-7 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>12/09/2003</u> . | 6) <input type="checkbox"/> Other: ____ |

DETAILED ACTION

Priority

Applicant's claim for domestic priority under 35 U.S.C. 119(e) is acknowledged.

Specification

The disclosure is objected to because of the following informalities: Text is missing in line 2 on page 27. Appropriate correction is required.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-4 are rejected under 35 U.S.C. 102(b) as being anticipated by Qin et al. { Qin et al. (1993) Genomics et al. 16 :580-585}.

As instantly recited, claimed invention is drawn to any composition comprising an isolated fragment of human genomic DNA comprising a nucleotide sequence encoding SEQ ID NO:1, wherein Xaa is isoleucine or threonine and further comprising a carrier capable of introducing the isolated DNA molecule into a mammalian cell.

A sequence comparison search of SEQ ID:NO:1 revealed that it has 100% similarity with the human IL-18/GILF sequence Q14116, wherein Xaa is threonine. The human GILF/IL-18

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locus maps to 11q22.2-q22.3 {Kalina et al. (2000) *Scan. J. Immunol.* 52, 525-530}. Therefore a genomic DNA fragment comprising human chromosome 11q22.2-q22.3, inherently encodes SEQ:ID NO:1.

Qin et al. provides guidance on the construction of a yeast artificial chromosome library (YAC) for human chromosome 11, with fourfold coverage of human chromosome 11 (Abstract). Further Qin et al. teaches that multiple YAC clones were prepared that covered region 11q22.2-q22.3 (Fig. 3, pg. 583). Further, Qin teaches isolation of chromosome 11 fragments, ligation into the pYAC4 vector and incubation in dialyzing buffer prior to transformation (Materials and Methods, pg. 581). Thus, by teaching all the limitations of the claims as written, Qin et al. anticipates the instant invention as claimed.

Double Patenting

A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

Claims 1-7 are rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 1-4, 6-8 and 12 of prior U.S. Patent No. 6,060,283. Although the conflicting claims are not identical in language, they are identical in content and scope of the subject matter. This is a double patenting rejection.

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Claim 1 of U.S. Patent No. 6,060,283 is drawn to an isolated DNA molecule comprising a nucleotide sequence encoding SEQ ID NO:1, wherein Xaa is isoleucine or threonine; wherein said nucleotide sequence consists of a fragment of human genomic DNA. Claim 1 of the instant application is drawn to a composition comprising an isolated DNA molecule comprising a nucleotide sequence encoding SEQ ID NO:1, wherein Xaa is isoleucine or threonine and further comprising a carrier capable of introducing the isolated DNA molecule into a mammalian cell; wherein said nucleotide sequence consists of a fragment of human genomic DNA. Claim 7 of U.S. Patent No. 6,060,283, is drawn to a mammalian host cell transformed by an isolated DNA molecule comprising a nucleotide sequence encoding SEQ ID NO:1, which could be introduced by a carrier such as DEAE dextran, calcium phosphate, lipofection or viral infection (U.S. Patent No. 6,060,283; Col. 4, lines 20-26). Therefore the carrier of claim 1 in the instant application is not given any patentable weight because it does not limit the scope or content of claim 1, which conflicts with Claim 1 of U.S. Patent No. 6,060,283.

Claims 2,3 and 4 of the instant application are nearly identical in language, and identical in content and scope of the subject matter of claims 2,3 and 4 of U.S. Patent No. 6,060,283.

Claims 5,6 and 7 of the instant invention claims the same invention as claim 6 of U.S. Patent No. 6,060,283. Although the conflicting claims are not identical in language, they are identical in content and scope of the subject matter.

No Claims Allowed.

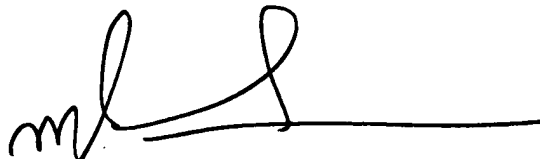
Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dr. Lou Lieto whose telephone number is (571) 272-2932. The examiner can normally be reached on Monday-Friday, 9am-5 pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Ram Shukla can be reached on (571) 272-0735. The fax phone number for the organization where this application or proceeding is assigned is (571)-272-0735. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Patent applicants with problems or questions regarding electronic images that can be viewed in the PAIR can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

Dr. Louis D. Lieto
Patent Examiner
Art Unit 1632



RAM R. SHUKLA, PH.D.
SUPERVISORY PATENT EXAMINER